UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

JUN 13 2018

BY EMAIL
RECEIPT CONFIRMATION REQUESTED

Jeff Jones
Authorized Agent to B3 Solutions LLC
14906 Horton St.
Overland Park, KS 66223

Subject: 90-day Preliminary Technical Screening Rejection
Product Names: BD-135
EPA File Symbols: 92807-R
Pesticide Petition Numbers: N/A
Date of Application: 11/17/18
OPP Decision Nos.: 536021
Company Name: B3 Solutions LLC

Dear Mr. Jones:

The U.S. Environmental Protection Agency (Agency or EPA) has completed its preliminary technical screening of your application pursuant to Section 33(f)(4)(B)(i)(II) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). Because you have not adequately responded to the data deficiencies identified in the 10-day deficiency letter dated March 12, 2018, the EPA has determined that your application did not pass the preliminary technical screening and therefore must be rejected.

Specifically, in a technical screening failure letter (also known as the 10-day letter) dated March 12, 2018, sent by email, the EPA notified you of the preliminary technical screening failure and your opportunity to correct your application within 10 business days of the receipt of that notice. You acknowledged receipt of this letter on March 12, 2018, during which time you were also notified that the response was due on March 26, 2018. On March 14, 2018, the EPA held a teleconference with you to discuss the contents of the preliminary technical screening failure letter dated March 12, 2018 (contained in the attached Confidential Appendix to this letter). You responded to the 10-day letter via email and electronic portal by citing data (MRID 505567-00 thru. 505567-06) submitted in a timely manner on March 26, 2018. Unfortunately, your submission did not adequately address all the Product

Chemistry, Acute Mammalian, and Product Performance data deficiencies identified in the 10-day letter from the Agency. In addition to the upgrades needed for your product chemistry data submission (MRID 505567-01), Acute Mammalian and Product Performance deficiencies were also noted, these included the following:

- The Acute Oral (GLN 870. 1100; MRID 50556704), Acute Dermal Irritation (GLN 870.2500; MRID 50556706), and Acute Eye Irritation (GLN 870.2400; MRID 50556705) data requirements on the end-use product (EP) were addressed with submitted data. However, you were required to address all the Tier I Acute toxicity data requirements for the EP, which included the above and following guideline (GLN) data requirements: Acute Inhalation (GLN 870.1300), Acute Dermal (GLN 870. 1200), and Skin Sensitization (GLN 870.2600). Your response to the 10-day letter did not address these EP data requirements. As a result, the Agency has determined that this deficiency was not fully resolved.

- You submitted preliminary video observations (via CD), which demonstrated how a group of sea gulls reacted when exposed to food items in the presence of the product (BD-135). However, you were required to submit product specific performance data to support the efficacy claims on the product label per 40 CFR 158.2070 (e.g., Duration of repellency up to 4 to 6 months and distance covered by repellency (12 ft cloud) must be validated with data). Furthermore, the video did not support efficacy claims made on the label. As a result, the Agency has determined that this deficiency was not fully resolved.

Because you have not completely resolved the deficiencies listed in the 10-day letter dated March 12, 2017, the EPA has determined that your application did not pass the preliminary technical screening and therefore must be rejected. For additional details associated with this action and the review of your response to the 10-day letter on March 26, 2018, please refer to Appendix - A attached to this letter (on page 3). Any future submission to the EPA will be considered a new application and subject to the full registration service fee, as well an additional initial content screening and preliminary technical screening.

If you have questions concerning this letter, please contact James Parker of the Biopesticides and Pollution Prevention Division by telephone at (703) 306-0469 or via email at parker.james@epa.gov.

Sincerely,

Richard P. Keigwin, Jr.
Director
Office of Pesticide Programs

Enclosure: *Appendix - A*

APPENDIX - A

Deficiencies Noted in the Technical Screen
EPA File symbol: 92807-R

Deficiency	Data/Information Submitted	Reason for Inadequacies	What Data/Information were Requested in the 10-Day Letter	Current Status of Outstanding Data/Information for this Application
OCSPP Guideline 880.1100 - Product identity and composition	MRID 504447-01	Data must be submitted in accordance with 40 CFR §158.320. No nominal concentrations of inerts, no function of inerts in the formulation, no upper and lower certified limits, and no Safety Data Sheets (SDSs) from suppliers of all formulation components listed on the Confidential Statement of Formula (CSF) for the basic and alternate formulations were submitted.	You must submit the following: nominal concentrations of inerts, function of inerts in the formulation, upper and lower certified limits, and SDSs from suppliers of all formulation components listed on the CSF for basic and alternate formulations.	The submitted data (MRID 505567-01, *Product identity and composition, Description of starting materials, Manufacturing process, Discussion of formation of impurities, Certified limits, and Enforcement Analytical method)* is **acceptable, pending resolution of items # 1, 2 and 3:** **1.** The manufacturing process should include amounts of each component added to produce the final amount of each product. The amounts of each component added to produce each product are needed. **2.** Your response states that Certified Limits (OCSPP 830.1750) are addressed in Appendix Cross Reference # 1 in MRID 505567-01. However, this section does not provide a signed Certified Limits Certification Statement, certifying the accuracy of the certified limits and that such limits will be maintained. A signed certification statement, certifying the
OCSPP Guideline 880.1200 - Description of starting materials, production and formulation process	MRID 504447-01	The manufacturing process for the basic and alternate formulations were not included; SDS from all suppliers of all active and inert components listed on the CSFs for basic and alternate formulations were not included.	You must submit a manufacturing process for both the basic and alternate formulations, and SDSs for all active and inert components listed on the CSFs for the basic and alternate formulations.	
OCSPP Guideline 880.1400 - Discussion of	MRID 504447-01	The submitted material does not include a discussion on the formation of impurities for the alternate formulation.	You must submit a discussion on the formation of impurities for the alternate formulation.	

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formation of impurities				accuracy of the certified limits and that such limits will be maintained are needed.
OCSPP Guideline 830.1750 - Certified limits	MRID 504447-01	No Certification Statement, certifying the accuracy of the certified limits and that such limits will be maintained, was signed and submitted by you. Just citing the CSF is insufficient.	A Certification Statement, certifying the accuracy of the certified limits and that such limits will be maintained, signed by the you must be submitted.	3. The enforcement analytical method was conducted on the basic formulation (Block formulation) and it is acceptable. The analytical method suitable for enforcement purposes is adequate to support determination of the concentration of same active ingredient in the alternate formulation for Granules, which is present in the alternate formulation at the same concentration as the basic formulation. • However, MRID 505567-01 needs to be upgraded to resolve lack of information concerning description of analytical methods and procedures. • Specifically, referenced Cross-reference #1 in Confidential Appendix for description of method and procedures employed in the analysis does not a provide detailed description of the method employed for the reported determinations of precision, linearity, accuracy, limit of detection, and coefficient of determination.
OCSPP Guideline 830.1800 - Enforcement Analytical methods	Data Matrix dated 01/26/18, cited MRID 473764-01, however data in MRID 473764-01 is for a different product: Rejex-it-Fog (a liquid formulation).	A method suitable for enforcement purposes is not provided for each active ingredient in the product according to 40 CFR §158.355. You are citing MRID 473764-01, a Rejex-it-Fog Force product. Product chemistry data is product specific and the test must be conducted on the product proposed for registration.	A method suitable for enforcement purposes must be provided for each active ingredient in the product according to 40 CFR §158.355.	

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				• The analysis report needs to be upgraded to describe procedures followed for: a) preparation of samples, stock and reference solutions, b) equipment employed and equipment calibration for analysis of samples, and for determination of spikes, that is peak absorption data. c) In addition, the study report needs to provide raw data, showing peak absorption for each sample replicate.
OCSPP Guideline 830.6302 - Color OCSPP Guideline 830.6303 - Physical state OCSPP Guideline 830.6304 – Odor OCSPP Guideline	Self-certification Summary for Physical/Chemical properties (PR Notice 98-1) Form dated 11/16/17.	Data must be submitted in MRID format for the applicable Physical/Chemical Characteristics. You are referring to the Summary of the Physical/Chemical properties (PR Notice 98-1) to satisfy these data requirements, listed on first left column of this table. The information provided in Form PRN 98-1 is insufficient because each one of the physical/chemical characteristics requires testing and the test	Data must be submitted for each of the applicable Physical/Chemical Characteristics listed. These data requirements, listed on the first left column of this table, should be submitted in a study report (MRID) and the study report must	You have submitted acceptable Physical and Chemical Characteristics data (MRID 505567-02 and MRID 505567-03) in response to the Agency's 10-Day technical screening failure letter.

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830.6313 - Stability to normal and elevated temperatures, metals and metal ions OCSPP Guideline 830.6315 - Flammability OCSPP Guideline 830.6317 - Storage stability OCSPP Guideline 830.6319 - Miscibility OCSPP Guideline 830.6320 - Corrosion characteristics OCSPP Guideline 830.7000 - pH OCSPP Guideline 830.7050 - UV/Visible light absorption		corresponding report must have been submitted (i.e. MRID cited) for each one of them.	include a description of test procedures, instrumentation, discussion of results, description of quality control/quality assurance procedures, and conclusion as applicable to each test.	

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OCSPP Guideline 830.7100 - Viscosity OCSPP Guideline 830.7200 - Melting point OCSPP Guideline 830.7220 - Boiling point/boiling range OCSPP Guideline 830.7300 - Density/relative density/bulk density OCSPP Guideline 830.7520 - Particle size, fiber length, and diameter distribution OCSPP Guideline 830.7550; 830.7560; 830.7570 -				

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Partition coefficient (n-Octanol /Water) OCSPP Guideline 830.7840 - Water solubility OCSPP Guideline 830.7950 - Vapor pressure				
CSF	CSFs dated 11/17/17	The purpose of garlic in the formulation as stated in the CSF is "non-target repellent", but it is neither listed as an active ingredient on the CSF nor listed as active ingredient on the label.	The EP has 2 active ingredients, including garlic. Garlic is a repellant and therefore must be listed on the CSF as well as declared as an active on the label. Furthermore, the name and concentration of both active ingredients must be consistent between the label and CSF. In addition, if garlic is listed as a repellent on the CSF and it is not supplied by a registered	The CSF has been revised to amend the purpose of garlic in the formulation from "non-target repellent" to "aversive" agent. The term "aversive" agent doesn't qualify as an inert ingredient. Therefore, a preliminary (5-batch analysis) must be submitted for the unregistered source of the TGAI for Garlic according to OCSPP Guideline No. 830.1700. Alternatively, if documentation demonstrating that the unregistered source of TGAI is obtained from a food grade source, five certificates of analysis from five individual batches of the TGAI may be submitted in lieu of a 5-batch analysis.

Deficiency	Data/Information Submitted	Reason for Inadequacies	What Data/Information were Requested in the 10-Day Letter	Current Status of Outstanding Data/Information for this Application
			source, it will have to satisfy all applicable technical grade active ingredients (TGAI) data requirements for their unregistered source of garlic; including product chemistry, toxicology and Tier-1 non-target organism data requirements, listed in 40 CFR 158.2030 - 2060 (as noted in Appendix 1 "Garlic TGAI Data Requirements") A preliminary (5-batch analysis) must be submitted for the unregistered source of the TGAI for Garlic according to OCSPP Guideline No. 830.1700. Alternatively, if documentation demonstrating that the unregistered source of TGAI is obtained from a food grade source, five certificates of analysis from five individual batches of the TGAI	

Deficiency	Data/Information Submitted	Reason for Inadequacies	What Data/Information were Requested in the 10-Day Letter	Current Status of Outstanding Data/Information for this Application
			may be submitted in lieu of a 5-batch analysis. In either circumstance, all impurities in the formulation must be identified.	
Acute Toxicity Data 870. 1100 - Acute oral 870. 1200 - Acute Dermal 870.1300 - Acute Inhalation 870.2400 - Acute Eye Irritation 870.2500 - Acute Dermal Irritation 870.2600 - Skin Sensitization	MRID 504447-02 Bridging rationale. Bridging to data on TGAI in MRIDs 426088-02 thru 426088-06.	Bridging to data for active ingredient methyl anthranilate, Technical active ingredient (TGAI) in MRIDs 426088-02 thru 426088-06.	Tier I Acute toxicity data requirement must be addressed for EP product. Each data requirement listed on first right column has to be addressed individually either with data or waiver rationale.	You submitted Acute Oral (GLN 870. 1100; MRID 50556704), Acute Dermal (GLN 870. 1200; MRID 50556706), and Acute Eye Irritation (GLN 870.2400; MRID 50556705) data which were categorized as acceptable. The toxicity categories for these routes of exposure are IV. However, the Acute Inhalation (OCSPP 870.1300), Acute Dermal Irritation (OCSPP 870.2500), and Skin Sensitization (OCSPP 870.2600) data requirements need to be addressed either with data from substantially similar formulation or rationale in lieu of actual study.

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Product Performance	MRID Numbers: 45020901-04; 450292-01; 450321-01; 455471-01; 455471-02; 456291-01; 456291-02	Product performance data depends on many particular aspects of the products as formulated packaged and applied. The current request is to bridging old data from Bird Shield Repellent Corp is inadequate and these studies are considered supplemental information only. They do not support efficacy claims on the product label such as duration of repellency up to 4 to 6 months, and distance of the cloud (12 ft), because this product is different from existing registered products in that it is a slow release solid formulation, whereas existing products are liquids or foggers.	A product specific performance study must be conducted to support the efficacy claims on product label. The following bird species need to be tested for efficacy: pigeons, geese, starlings, sparrows, American crows, finch, and doves. Duration of repellency up to 4 to 6 months must be validated with data. Distance covered by repellency (12 ft cloud) must be validated with data.	You addressed the product performance data requirement with preliminary observations from a video tape, consisting of responses from a group of sea gulls exposed to food items in the presence of the product. The birds did not eat the food that was encircled by the product, but the presence of the product did not prevent the birds from moving near the product, and even try to catch pieces of food when the food was placed near, but outside the repellent circle. The product did not repel the birds from its vicinity nor prevented them from trying to catch food near the product when it wasn't encircled by it. Furthermore, the set up and arrangement of the product in relation to food items is not representative of the use pattern described on the label regarding the number of blocks or pouches needed to protect space of 1,000 ft^3.

Shortcomings Noted in the Preliminary Technical Screen
EPA File symbol: 92807-R

Deficiency	Data/Information Submitted	Reason for Inadequacies	What Data/Information are Needed	Current Outstanding Data/Information for this Application
CSFs and Label	Basic and alternate formulation CSFs dated 11/17/17, and draft product label	The name of the active ingredient (a.i.) does not match the name of the a.i. listed on the CSF.	The CSFs and/or the label must be amended to resolve this inconsistency.	You have corrected the discrepancy between the label and CFS concerning the name of the active ingredient, Methyl Anthranilate, which is now named consistently on both labels and CSF.